DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Submission Tracking Number (STN): 103922/5001

MAR 07 2001

Jim C. Williams, Ph.D.
Aventis Pasteur Inc.
Discovery Drive
Swiftwater, PA 18370

Dear Dr. Williams:

The Supplement to your License Application for Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (Tripedia®), to include a preservative-free, single dose vial presentation, has been approved.

Under this approval, lots of single dose preservative-free Tripedia® shall have an expiration dating period of 18 months when stored at 2-8° C. Any requests to extend the dating period beyond 18 months will require the submission of supporting data as a Supplement to your License Application for review and approval.

We acknowledge the following commitments outlined in your submissions of February 9 and March 5, 2001, and in a telephone conversation held on February 22, 2001, between personnel from the Center for Biologics Evaluation and Research (CBER) and personnel from Aventis Pasteur Inc.

1. Real time stability data on final containers for lots U0309A, U0310A, and U0311A, will be accumulated at the following intervals: 6, 9, 12, 18, 24, and 36 months, and these stability data will be provided to CBER as they become available. In addition, you have agreed, in your letter of March 5, 2001, to submit stability data from your Bulk Vaccine program at the 9 and 12-month time points as soon as those data are made available.

2. Validation studies on the manufacturing process for the Tripedia® vaccine, to include the production of the diphtheria and tetanus toxoids and the formulation of the final product will be conducted. You have agreed, in your letter of March 5, 2001, to submit validation protocols regarding the manufacturing of the preservative-free Tripedia® to CBER no later than April 2001, and that all validation studies will be completed no later than second quarter 2002. You have also agreed to submit status reports at six-month intervals describing the progress of the Tripedia® preservative-free validation studies.

Please submit four copies of final printed labeling at the time of use and include the label transmittal Form FDA 2567 (5/99) with completed implementation information.

This information will be included in your License Application file.

Sincerely yours,

Richard I. Walker, Ph.D.
Director
Division of Bacterial, Parasitic
and Allergenic Products
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Attachment: Approved Package Insert Labeling/Form 2567